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# ACT-HIB

*Sanofi-Pasteur*

## Composition

Haemophilus type b Conjugate Vaccine Powder

- Haemophilus influenzae* type b polysaccharide conjugated to tetanus protein - 10 µg**
- Trometamol
- Sucrose for one immunizing dose

* strain IM 2164
** corresponding to the quantity of purified polysaccharide

*Diluent*

- Sodium chloride
- Water for injections for one 0.5 ml immunizing dose

## Pharmaceutical Dosage Form

Solution for injection, obtained by reconstituting the powder in the single-dose vial with a syringe of diluent (0.5 ml).

## Indications

This vaccine is indicated for the prevention of invasive Haemophilus influenzae type b infections (meningitis, septicaemia, cellulitis, arthritis, epiglottitis,...) in infants from 2 months of age.

It does not provide protection against infections due to other types of Haemophilus influenzae, nor against meningitis caused by other microorganisms.

## Contraindications

This medicinal product Must Not Be Used in the following cases:

- Known allergy to one of the ingredients of the vaccine, particularly tetanus protein or allergy appearing after a previous injection of conjugate Haemophilus influenzae type b vaccine. If there is any doubt, it is essential to consult your doctor or your pharmacist.

## Side Effects

Like any active product, this medicinal product may in certain persons cause effects which are disturbing to a greater or lesser extent. Report to your doctor or to your pharmacist any unwanted and disturbing effects which might not be mentioned in this book.

## Warnings and Precautions

- Do not inject by the intravascular route make sure that the needle does not penetrate a blood vessel.
- Vaccination should be postponed in those suffering from fever or acute disease, particularly infectious disease or progressive chronic disease.
- An immunosuppressive treatment or immune deficiency may induce a decrease in the immune response to the vaccine.
- If the vaccine is coadministered with the Measles-Mumps-Rubella vaccine, and the Diphtheria, Tetanus, Pertussis. Poliomyelitis vaccines, the vaccines will be administered at two separate injection sites.

If there is any doubt, do not hesitate to consult the doctor or the pharmacist.

Keep out of the reach of children.

## Storage

Do not exceed the expiry date stated on the external packaging.

This medicinal product should be stored at a temperature of between + 2oC and + 8oC (in a refrigerator).

Do not freeze.

## Drug Interactions

In order to avoid possible interactions between several medicinal products, any other ongoing treatment should be systematically reported to the doctor or to the pharmacist.

## Dosage and Administration

In any case, strictly conform to the doctor's prescription.

- Before 6 months of age, 3 successive 0.5 ml doses at one or two month intervals followed by a booster injection (0.5 ml) at 18 months of age.
- Between 6 and 12 months, two 0.5 ml doses at a one month interval followed by a booster injection (0.5 ml) at 18 months of age.
- From 1 to 5 years, a single 0.5 ml dose.

**Mode and Route of Administration**

Reconstitute the powder in the Act-HIB vial (1 dose) with a diluent syringe (4% sodium chloride solution) or a syringe of D.T.COQ/D.T.P. (adsorbed diphtheria, tetanus and pertussis vaccine) or TETRACOQ (adsorbed diphtheria, tetanus, pertussis and inactivated poliomyelitis vaccine).

Shake until complete dissolution of the powder. The cloudy, whitish appearance of the suspension after reconstitution with a syringe of D.T.COQ/D.T.P. (adsorbed diphtheria, tetanus and pertussis vaccine) or TETRACOQ (adsorbed diphtheria, tetanus, pertussis and inactivated poliomyelitis vaccine) is normal.

Administer preferably via the intramuscular route or via the deep subcutaneous route; the recommended injection sites are the antero-lateral side of the thigh (middle third) or the superoexternal gluteal region in infants and the deltoid region in children.

Do not inject by the intravascular route.

**Packaging**

v: single dose + 0.5 ml diluent